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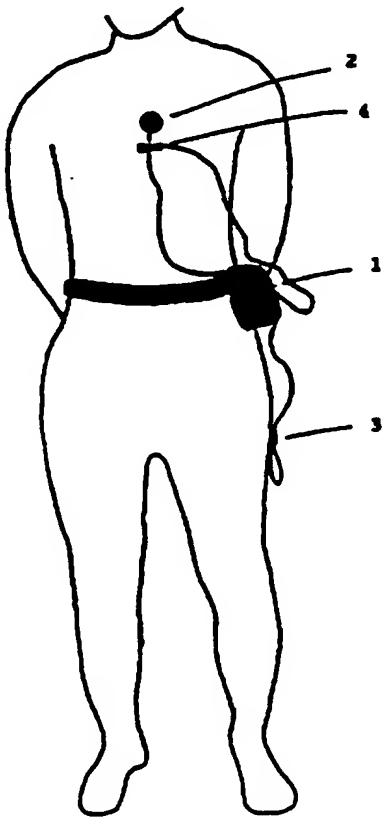
(54) Title: ACTIVITY RECORDING DEVICE

(57) Abstract

A device and a method for monitoring activity. The device is adapted to record information relating to posture and number and vigour of steps in real time over prolonged periods. The device includes position sensors (5) and an accelerometer (4). Data is processed through an interface (7) and stored on a computer. The device provides means for a user to input subjective information, typically periodically.



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ACTIVITY RECORDING DEVICE

The invention relates to a portable device, and method, for the simultaneous recording of user activity and user assessment of any subjective perception.

The measurement of physical activity may have many applications. Physical activities, spontaneously undertaken, will be partially determined by ability to exercise, and may therefore be a useful and objective measure of disability. It may also have use in the surveillance of recommended exercise regimes and the physical activity demanded by different occupations. It may also be useful as a measure of activity in people who are incompetent to answer questions, such as young children or adults with dementia. Adherence to sports training regimes and the quantification of energy used to complete tasks undertaken in a natural environment may also be assessed by monitoring physical activity.

In addition to the above the invention finds application in any condition which produces a chronic disability. In this category one would include virtually all neuromuscular conditions, ageing, restriction of activity by angina, restriction by breathing problems such as bronchitis, restriction by anaemia, pain from other causes, peripheral vascular disease and restriction of activity by mood as in depression.

In the following description of the invention the invention is described having regard to the subjective perception of pain or discomfort. However, it is to be understood that the application is not to be limited in this way, rather the application is intended to cover any subjective perception which may be of clinical and/or surveillance value in determining the well-being of an individual. For example, the subjective perception of stiffness, tremor, comfort, contentment, thirst, noise levels or indeed any other subjective perception is intended to be included in the scope of this application.

In addition, in the following description of the invention the invention is described having regard to an event recording means. This event recording means can be used to record any event such as a fall or even a more subjective event such as an attack of angina. However, it is not intended that the application should be limited to either of the foregoing examples. Rather, the event recording means can be used to record any event which may be used to assess user activity.

It is envisaged that the invention will find particular application in a number of situations where monitoring of the activity and/or pain of the user is required.

For example, it is predicted that the invention will find utility in monitoring the improvement or deterioration in the symptoms of a medical patient in response to nursing and/or drug therapies, particularly, in respect of chronic neurodegenerative diseases such as Parkinson's Disease, and in respect of other degenerative diseases such as Rheumatoid Arthritis. It is predicted that the information obtained from monitoring using the invention will enable the effectiveness of a given therapy and/or nursing regime to be determined more accurately and inexpensively, and accordingly optimised more quickly.

In addition, it is predicted that the invention will find utility in testing the toxicology, potency and efficacy of drug therapies, enabling pharmaceutical companies to develop drugs more rapidly, inexpensively and effectively than they are able to do currently.

Specifically, for example, it is envisaged that the invention will find application in monitoring the response of patients suffering from Rheumatoid Arthritis to drug therapies, particularly to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

General Background

Accurately monitoring the response of patients suffering diseases, particularly chronic neuro-degenerative diseases, such as Parkinson's Disease and Alzheimer's Disease, and/or also chronic arthritic diseases such as Osteoarthritis, and Rheumatoid Arthritis, is vital to enable the clinician to assess the effectiveness of a particular drug or nursing therapy. Such accurate information allows the clinician to either use or discard a drug on intervention or treatment as necessary, in response to the patient's symptoms.

Furthermore, pharmaceutical companies require accurate data when developing novel drug therapies. This is the case particularly when information on the effects of the drug on the human body is required. Before being sold to the general public, all novel drug therapies must undergo trials on human volunteers. Such human trials are necessary in order to assess the efficacy, potency, and most importantly the toxicological effects of the drug. The provision of data following human clinical trials of drugs is often the final hurdle in a long term development programme, and is the culmination of vast amounts of research effort and expenditure. Failure at this last, and most important stage, often means that the years of research and development are wasted.

Furthermore, conducting human trials requires many volunteers for the trials to be statistically reliable, which of course they must be if the results of the trial are to be acceptable to the Drug Authorities. It is a fact that these trials themselves demand great expense and organisation and it is therefore vital that accurate information is obtained.

The consequences of releasing a drug for sale to the general public which has not been effectively screened, and later proves to have serious side effects on

the patient, are immense. For example, the drug Thalidomide developed to reduce morning sickness in pregnant women, was later found to cause serious birth defects in some cases, and has resulted in multi-million pound claims for compensation from victims. This case emphasises the importance of obtaining accurate information from human trials.

Obtaining accurate data on the effects of drug therapies, whether in clinical therapy or pharmaceutical drug development, may require information gathered over long time periods to enable statistically significant information to be obtained. Furthermore, the occurrence of undesirable side-effects may not appear for some considerable time and the manifestation of these side effects may be slow to develop, but detectable during reliable chronic assessment.

Many diseases, especially the chronic neuro-degenerative type diseases, such as Parkinson's Disease and Alzheimer's Disease, and chronic arthritic diseases such as Osteoarthritis and Rheumatoid Arthritis, are particularly difficult to monitor and obtain accurate information on levels of discomfort and pain. This is because the symptoms vary depending on a large number of factors, such as, activity, time of day, the patient's state of mind, ambient temperature etc.

For example, consider Rheumatoid Arthritis. Rheumatoid Arthritis is a complex and frustrating disease. The pathological process of Rheumatoid Arthritis is composed of acute inflammation, chronic immunological phenomena, and chronic connective tissue degradation. To further complicate the picture, a variety of incomplete forms of Rheumatoid Arthritis exist. The degree of pain and discomfort endured by sufferers of Rheumatoid Arthritis depends on a number of external factors, such as, type of activity undertaken, degree of exertion, time of day, ambient temperature. Statistics indicate that the incidence of clinical symptoms is higher in cold damp areas.

The techniques used to monitor degenerative diseases and the effect of a particular therapy, have typically fallen into two categories:

1. A clinician/researcher conducting an interview with and/or examination of the patient/volunteer.

2. A diary maintained by the patient/volunteer in which the patient/volunteer records the symptoms at a particular instant in time.

The Ritchie Index is an example of the former. It is a method used by clinicians to monitor and gather data on the symptoms of patients suffering from Rheumatoid Arthritis. In particular, this method has found application in monitoring the effects of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) on the symptoms of Rheumatoid Arthritis. The method has found favour amongst Rheumatologists due to its simplicity and quickness. This method has been recognised by the Standing Committee on International Clinical Studies.

The principle of the method is based on joint tenderness, and involves a Rheumatologist applying digital pressure to key joint margins. Joint tenderness is considered by many Rheumatologists to be the most reliable clinical parameter of joint inflammation and hence the most accurate at reflecting the severity of the underlying inflammatory process involved in Rheumatoid Arthritis.

With the Ritchie Index, joint tenderness is tested for in each of the following joints:

Temporomandibular Joint, Cervical Spine, Sternoclavicular, Acromioclavicular, Shoulders, Elbows, Wrists, Metacarpophalgeal, Proximal Interphalangeal, Hips, Knees, Ankles, Talocalcaneal,

Midtarsals, Metatarsals.

With the Ritchie Index the degree of joint tenderness is graded as follows:

Grade 0	The patient has no tenderness
Grade 1	The patient complained of pain
Grade 2	The patient complained of pain and winced
Grade 3	The patient complained of pain, winced, and withdrew

The individual scores for each joint are summated to provided a score range from 0 to 78.

However, the degree of joint tenderness is considerably influenced by the amount of pressure applied by the examiner, and therefore an accurate comparison of data is not possible unless the tests are performed by the same examiner.

A further example of the category 1 type of monitoring technique, is called the Health Assessment Questionnaire (HAQ). It was developed as a "multidimensional paradigm" designed to probe dimensions of discomfort and disability caused by Rheumatoid Arthritis. It can be used to assess changes in disease activity over several months, or to monitor the effectiveness of a particular therapy.

The HAQ measures physical disability in eight component categories: dressing and grooming, arising, eating, walking, hygiene, reach, grip and outside activity.

Each category contains one or more questions, and the patient's responses are recorded on a 4-point adjectival scale, i.e. could they do the task asked by the

HAQ;

without any difficulty
with some difficulty
with much difficulty
unable to do so

It will be apparent that where an individual responds to a questionnaire and is able to undertake some task either without any difficulty or, alternatively, is completely unable to undertake a certain task then the individual is off the scale. The questionnaire is therefore limited in this respect. This is in complete contrast to the invention of this application because the invention can be used to monitor, in respect of activity, either complete inactivity, typically characterised by bed rest, or alternatively, extreme exertion such as running, climbing or the like.

An example of the method described in category 2 is the 24 hour Diary Pain Severity Record. This methodology is typically used to monitor the pain suffered by a patient over a period of 24 hours and as such is often used to complement the "snap shot" approach of the Ritchie and HAQ methods. The 24 hour Diary method involves the patient describing the pain level and is therefore highly subjective. The most commonly used scale on which to assess pain, particularly when applied to Rheumatoid Arthritis sufferers, is the Likert Scale. This is an adjectival scale consisting of 5 categories:

no pain, mild pain, moderate pain, severe pain, very severe pain

The patient then records in the diary the category of pain which they feel is most descriptive of their pain situation.

Problems with The Prior Art

Methods for monitoring the condition of a patient which rely on the clinician conducting an examination of a patient or volunteer, such as the Ritchie method for assessing the discomfort level of Rheumatoid Arthritis sufferers, provide an accurate measurement of pain at that instant in time. However, this method provides only a "snap shot" of the discomfort which the patient has been suffering, and it is possible that this "snap shot" does not provide an accurate picture of the patient's symptoms.

For instance, the Ritchie method involves the clinician exerting pressure onto the joint area. It is probable that each clinician will apply differing amounts of pressure to the joint areas, and as such results can only be accurately compared between examinations performed by the same clinician.

Furthermore, examination methods such as the Ritchie method are susceptible to human error, that is to say that the same clinician may not apply the same degree of pressure to the patient's joints on each examination of the patient.

In addition, examination methods such as the Ritchie method may not locate the area of the patient's body actually causing most pain. As a result the examination will not pin-point the extent of the patient's symptoms.

Furthermore, the results of a one-off test, such as the Ritchie test will depend both on the type and extent of activity the patient has been partaking in prior to the examination. In addition, external factors such as the ambient conditions, the time of day are likely to affect the results.

Interview methodologies such as the HAQ method are based on the patient recounting the disability they have experienced during the period prior to the

interview.

Such interview methodologies are prone to problems of inaccurate recollection.

A further problem with the interview methodologies is that the questions are often very specific, and it may well be the case that the patient suffers most disability for an activity which the questionnaire does not cover.

The 24 hour diary method provides a more complete picture of the patient's symptoms. However, it is time consuming for the patient to complete the diary and also requires the patient to remember to fill in the diary at the specified time. In addition, it is likely that the patient may forget to maintain the diary, or worse, to fill it in retrospectively.

Furthermore, the patient must record not only the level of discomfort felt at the specified time, the patient must also record and describe his/her activity during the previous period. Accurate recording of such information is open to errors as degree of exertion is difficult to quantify accurately.

It is therefore an object of the invention to provide an accurate and preferably continuous record of an individual's activity, and to relate that information to an individual's own assessment of a subjective parameter such as pain, in such a fashion that will avoid for example the inaccuracies of infrequent examinations and questionnaires.

It is a further object of the invention to reduce the reliance on examination methods to monitor a subjective parameter such as patient pain and discomfort level, and in addition to avoid the errors which are inevitable when examinations are conducted by different clinicians/therapists.

It is a further object of the invention to accurately and objectively record a user's activity and the time of activity.

It is a further object of the invention to provide a subjective means for recording a subjective parameter, such as pain level, and to relate that subjective parameter accurately to an objective activity record.

It is a further object of the invention to provide a device which is simple and quick to use, and in addition which prompts a user at predetermined intervals to enter subjective information.

It is a further object of the invention to provide a sensing means which quantifies the degree of exertion involved in the activity as well as defining the actual activity itself.

According to a first aspect of the invention there is provided a portable device for sensing and recording parameters relating to the well-being of a user which comprises:

at least one sensing means functionally coupled to a recording means whereby information from said sensing means can be recorded on said recording means; at least one input module adapted to allow said user to enter subjective information which information is also recorded on said recording means and further wherein said recording means is adapted such that said information can be selectively recalled when required.

In a preferred embodiment of the invention said input module is removable.

In a preferred embodiment said sensing means continuously monitors the activity of said user.

In a preferred embodiment of the invention said sensing means comprises at least one posture sensing means, but preferably at least two posture sensing means. One of said two posture sensing means is preferably positioned on the trunk of the patient, the other posture sensing means is preferably positioned on the thigh, so that in combination, said posture means enables a clinician to determine the patient's activity, ie lying, standing, sitting. Preferably, at least one of said posture sensing means comprises a mercury column.

In a further embodiment of the invention said sensing means comprises at least one acceleration/deceleration detecting means, which preferably comprises a piezo-electric crystal.

In a further embodiment of the invention said sensing means comprises a heart beat detecting means.

In a further embodiment of the invention there is a facility which intermittently prompts the user to enter said subjective information into said input module. Preferably further still said facility is programmable so as to prompt a user at preselected time intervals. Preferably, said facility includes an audible alarm.

In a further embodiment of the invention said input facility includes a manual inputting means, preferably a thumb-wheel switch including a graduated scale.

More preferably still, said invention includes an event button which a user can press to record an event such as a fall or an attack of angina, or indeed any other event.

In a preferred embodiment said recording means comprises a microprocessor, for example a PSION Series 3. Preferably said recording means also includes said recall means.

In a preferred embodiment said input module is functionally coupled to said recording means *via* an interface module.

More preferably still, a display means is provided for the purpose of displaying said information.

Ideally said invention further includes a disabling means which disables the device when a user is sitting or lying, and preferably also a monitoring means is also provided to periodically check whether the user has resumed activity, and if so to reactivate the device.

In a second aspect of the invention there is provided a method for sensing and recording parameters relating to the well-being of user, which comprises:

sensing a user's activity using a sensing means and recording said activity on a recording means functionally coupled thereto;

entering subjective information in to at least one input module which information is also recorded on said recording means; and

selectively recalling said recorded information as required.

Preferably said information is also displayed, after recall, for the purpose of assessment.

Diagrams

The invention will now be described by way of example only with reference to the following Figures, wherein:

Figures 1 and 2 show the invention as worn by the user.

Figure 3 is a diagrammatic representation of an embodiment of the invention.

Figures 4 to 9 show recordings taken using the device.

Figure 10 shows a graph illustrating that the device of the invention can be used to measure energy used during activity.

Figure 11 shows the relationship of pain scoring to activity during a day when the invention is in use.

Tables 1 to 4 show validation data relating to the device of the invention.

Table 5 shows a table containing some of the results from a typical 24 hour trial obtained from using the invention.

Figures 1 and 2 show two views of the invention as worn by a user. Figure 1 shows the recorder (1) as worn around the waist of the user. The posture sensing means are shown on the trunk (2) and on the thigh (3). The accelerating means (4) is also shown positioned on the trunk of the user adjacent the posture sensing means beneath the posture sensing means.

Referring to Figure 3 there is shown a diagrammatic representation of an embodiment of the invention. The left hand side of Figure 3 depicts the sensing means (5) of the invention. The sensing means consists of at least one, and preferably two, posture sensing means which typically contains a mercury column.

In use, one of the posture sensing means is positioned on the trunk of the user

and another posture sensing means is positioned on the thigh of the user. In addition to, or alternatively, the sensing means may include an acceleration/deceleration sensing means, and/or may include a heart beat sensing means.

The sensors are encapsulated in silicone rubber compound for their protection and the patient's comfort, and are attached to the skin using an adhesive film.

The sensing means (2, 3) are shown in Figure 3 connectively coupled to an input module (6) which is shown in the centre of the Figure. The input module is connectively coupled to an interface module (7) which is in turn connectively coupled to the recording means (8). It can thus be seen that all components are connected in series. Figure 3 also demonstrates the flexibility of the invention, in that if desired, the sensing means (5) can be connectively coupled directly to the interface module (7), so bypassing the input module.

The input module (6) is shown in the centre of Figure 3. The input module includes typically a graduated thumb wheel switch which the user operates to enter subjective information, such as pain assessment.

The recording means (8) is shown in the right hand side of Figure 3 and is shown as a PSION Series 3 microprocessor. In the case of the PSION microprocessor this recording means also includes a recall means.

More specifically the components of the device are as follows.

Position Sensing (2, 3) - The patient's position is detected by two sealed mercury switches, which close a circuit if they are within 45° of the vertical position. One switch is attached to the chest over the sternum and the other to a thigh. The state of these two switches gives an indication of overall position

divided into three categories: standing (chest and thigh vertical), sitting (chest vertical and thigh horizontal) and lying (chest and thigh horizontal).

Accelerometer (4) - During periods of standing the patient's activity is monitored by an accelerometer, sensitive to vertical motion, attached to the patient's chest. the output of the accelerometer allows period of walking and individual steps to be identified, and gives an indication of walking vigour. It is made from a horizontally mounted piezo electric element weighted at one end and fixed at the other. This has voltage output which is proportional to the rate of change of acceleration. The piezo element output is buffered by a pre-amplifier mounted within the sensor assembly.

Interface Module (7) - The sensors are connected to the microcomputer via an interface module. This communicates with the computer via a high speed serial data link, and contains electronic circuits to process accelerometer signal and combine it with the switch information. The interface module is adapted for the Psion RS-232 link module.

The analogue signal from the accelerometer is integrated, to convert it to true acceleration, low pass filtered at 10Hz to remove unwanted high frequency information, amplified then digitised at a sampling rate of 20Hz. The amplifier gain is adjusted so that the output of the 8 bit digitiser, with a range of 0 to 255, corresponds to an acceleration of approximately -10 to +10m/s^2, negative representing an acceleration upwards.

Computer (8) - This is a standard Psion Series 3. Data is stored in removable 'Solid State Disks' (SSD), a typical day's recording requiring about 500k bytes. A single recording session generates three or more data files. All the files have an identical plain text header containing a unique machine identification code, the patient identification code and the date and time of recording start.

First is a record file, containing position changes and the time of day they happened, the number of samples of accelerometer data recorded for each period of standing, and total time spent in each position.

Second is a sample file containing a string of bytes being the 20Hz sampled accelerometer data.

Third is a patient input file, containing the setting of the numbered switch for each of the half hour time slots during the day.

During monitoring the current position, time, and accumulated times spent in each position are displayed. If subjective information is required from the patient, an alarm sounds at appropriate intervals, usually half hourly. To conserve the batteries when recording for periods longer than 24 hours the system switches itself off when the patient is sitting or lying, and hence accelerometer information is not being sampled During these periods the machine switches on briefly every ten seconds to check whether the patient's position has changed. The positional information will therefore have a time resolution of ten seconds when used in this mode.

Analysis

The positional data (stand, sit, lie) are reorganised into time periods. The duration and the start time of these periods could be selected in the range 1 minute to 360 minutes. the accelerometer record was analysed to detect the occurrence and amplitude of steps. These were also analysed in the time periods as a count and mean (with standard deviation) respectively. Step detection relied on the recording of the vertical impulse at heel strike by the accelerometer mounted on the sternum. The following rules were used to detect the impulse.

1. The peak must exceed a given threshold level, peaks below this level were assumed due to background noise.
2. The acceleration data must return to values below the threshold after the peak.
3. In the event of detecting more than one peak prior to return to threshold, the larger peak was recorded.
4. No two impulses could occur less than 0.3 seconds apart, this prevented the double counting in the event of high levels of noise but did impose a maximum cadence of approximately 3 steps per second. The threshold and the minimum time between steps could be adjusted by the user, however the default values of 136 and 0.3 seconds respectively were found to be robust in validation studies with the patient group.

A variety of displays were available, the data could be visualised over 24 hours, 5 hours, 15 minutes or 50 seconds. In each case the position was represented by a line against either stand, sit or lie and steps were represented by dots plotted as amplitude against time. In the case of the 50 second display the acceleration trace was also shown allowing the user to inspect the outcome of the automatic step detection. In addition, a summary table could be generated. This could either be printed or exported as a comma separated value (CSV) file. The exported file was compatible with a variety of spreadsheet and graphics packages which allowed for further analysis and display of the data.

Another way of viewing the data contained in the program is as a histogram of step number against amplitude. The number of times the accelerometer reaches the extreme of its movement is counted prior to analysis, as a high frequency may indicate a problem with the accelerometer or a broken wire.

Results

Figure 4 shows a sample recording from the machine: A fifty second period out of a twenty-four hour recording, showing the change in posture from lying to sitting, to standing still, walking slowly and walking more briskly.

Figure 5 shows a typical 24 hour recording in 24 hour summary with each dot representing a step, the further away from the base line, the greater the amplitude. A typical day's activity and night lying is shown.

Validation Against Observation

The machine was worn while the subject walked fifty paces briskly. The recording of this is shown in Figure 6 and again shows good agreement with the activity undertaken. More realistic spontaneous activity was undertaken wearing the machine and the activity recorded on video. The video was then observed by two independent observers and the activity, in terms of steps, counted. These were then compared with each other and with the recording, and the results are summarised in Table I. There was as much variation between the observers as there was between either observer and the recording. Ninety-five percent limits of agreement was within ten steps and similar to the agreement between observers. There was no systematic error detected.

Validation - Agreement between machines

Two separate machines were worn simultaneously by the same person over the same period of time. Figure 7 shows the similarity of the traces. Table II compares the amplitude recorded of the activity from two machines from two such simultaneous recordings and one recording of three machines with sensors applied adjacent each other. Ninety-five percent limits of agreement are within

3.2 amplitude units which represents a maximum 7% error at typical activity level.

Size of Recording

The amount of activity in a recording is in practice without limit and can vary from 24 hours rest through to heavy physical activity all day. A maximum of 72 hours continuous recording without change of batteries is possible.

Tolerability

We have now used the machine in more than 150 individual recordings of twenty-four hours or greater, and discomfort from wearing the machine was only complained of by two people. The weight of the machine at 600 g is of no limit to activity, and with the exception of getting wet, normal activity is possible. In the event that the device is to be used in instances where an individual can expect to get wet the device can be modified to be either be enclosed in a waterproof wallet, or alternatively, it can be made of waterproof materials, or substantially waterproof materials so that the outer-shell of the device prevents penetration of water.

Calibration of Energy Measurement

The product of number and average amplitude of steps for a period of time should reflect the energy used for physical activity during that period. We have calibrated this for treadmill activity in metabolic equivalents (METS) on 15 patients who wore the monitor whilst undergoing a Bruce protocol exercise test for suspected angina. The subjects were of varied height (1.69 ± 0.11m), weight (74.4 ± 14.3 kg) and age (57.7 ± 12.3 yrs). Results were analysed as energy output per minute, and plotted against the METS for each completed

stage. These results are shown in Figure V and show a very good linear correlation (r=0.98).

Usefulness

Week-to-week variation was assessed in a variety of normal subjects and rheumatoid arthritis patients. The machine was worn for the same period of the week on two consecutive weeks by nine different subjects. The results were summarised for 24 hours and are displayed in Table III. Energy expenditure between recordings was within 80% agreement. Day-to-day variation was assessed by recording subjects for 48 hours continuously. The first 24 hours was compared to the second. This was done for eight subjects and the results are summarised in Table IV. Agreement was around the 72% mark. These results show reasonable similarity of activity, week-to-week and day-to-day.

Assessing Disability

In order to assess activity in people with disability, energy output was measured over 24 hours in normals and compared with that of patients with mild rheumatoid arthritis defined as HAQ between 0.5 and 1.5, and those with severe rheumatoid arthritis defined as HAQ between 2 and 3. The results are displayed for average amplitude of step in Figure 8 and for energy use in Figure 9. As can be seen the normals were more active than the mild rheumatoid arthritis, who were more active than the severe rheumatoid arthritis. There was no more variation in energy use of the normals than the rheumatoids.

Referring to Table 5 there is shown a table containing some of the results from a typical 24 hour trial recorded using the invention. The trial is divided into 24 one hour monitoring periods.

The left hand side of the table contains the data obtained from the sensing means. The right hand side of the table contains further information resulting from computations based on the data from the sensing means.

The first column on the left hand side of the table contains the start time of each monitoring period. The duration of each monitoring period is one hour (3600 seconds) as shown in the second column of the table.

The third, fourth and fifth columns contain the time spent lying, sitting or standing respectively, during each one hour monitoring period.

The sixth column records the number of steps taken by the user during each one hour monitoring period and the seventh column records the statistical mean amplitude of the steps taken during the monitoring period, together with the standard deviation in the eighth column.

Columns 7 to 14 contain further information which has been generated by computation from the basic information obtained from the sensing means.

For example the twelfth column from the left contains the statistical mean of the time interval between steps taken during each one hour monitoring period.

Correlating Pain with User Activity

In order to assess the usefulness of the invention in determining a correlation between user activity and pain a plot was made of user activity during a single day with a plot of recordings relating to subjective user pain assessment.

It can be seen in Figure 11 that during the start of the day the user recorded relatively high levels of subjective pain assessment and correspondingly, user

activity was low. As the day progressed the user's perception of pain declined and as this happened there was marked increase in user activity. Interestingly, the user's assessment of objective pain declines throughout day, however a peak in this decline is matched with a peak in activity, possibly indicating that the increased activity may be responsible for the temporary increase in recognition of subjective pain.

The data in Figure 11 thus shows that the invention can be used not only to record user activity but also to correlate this activity with the user's perception of well being.

It is envisaged that different and more subtle analysis will be appropriate to different monitoring situations.

It can therefore be seen that the invention concerns the provision of a device adapted to measure chronically, and if preferred, continuously the well-being of an individual so that small or gradual or otherwise imperceptible or difficult to detect changes can be detected and monitored.

CLAIMS

1. A portable device for sensing and recording parameters relating to the well-being of the user which comprises: at least one sensing means functionally coupled to a recording means whereby information from said sensing means can be recorded on said recording means; at least one input module adapted to allow said user to enter subjective information which information is also recorded on said recording means and further wherein said recording means is adapted such that said information can be selectively recalled when required.

2. A device according to claim 1 wherein said input module is removable.

3. A device according to claims 1 or 2 wherein said sensing means continuously monitors the activity of said user.

4. A device according to any preceding claim wherein said sensing means comprises at least one posture sensing means.

5. A device according to claim 4 wherein said posture sensing means comprises a gravity detecting means.

6. A device according to claims 4 or 5 wherein two sensing means are provided.

7. A device according to claims 4 to 6 wherein said sensing means is adapted to be attached to the body of a user.

8. A device according to claims 4 to 7 wherein said sensing means comprises a mercury column.

9. A device according to any preceding claim wherein said sensing means further comprises at least one acceleration/deceleration detection means.

10. A device according to claims 1 to 3 wherein said sensing means comprises at least one acceleration/deceleration detection means.

11. A device according to claims 9 or 10 wherein said detection means comprises a piezo-electric crystal.

12. A device according to any preceding claim wherein said device further comprises a heart rate detector.

13. A device according to claims 1 to 3 wherein said sensing means comprises a heart rate detector.

14. A device according to any preceding claim which includes a prompt facility that is adapted to intermittently prompt the user.

15. A device according to claim 14 wherein said prompt facility is programmed so as to prompt a user at preselected time intervals.

16. A device according to claims 14 and 15 wherein said prompt facility includes an alarm device.

17. A device according to any preceding claim wherein said input module comprises graduation means whereby a user can input the magnitude of subjective information.

18. A device according to any preceding claim which includes an event button which a user can press to record an event.

19. A device according to any preceding claim which includes a display means for displaying said information.

20. A device according to any preceding claim which includes a disabling means adapted to disable the device when a user is stationary for a predetermined length of time.

21. A device according to claim 20 wherein said disabling device also includes a monitoring means adapted to periodically check whether the individual is stationary, and if not, to reactivate the device.

22. A method for sensing and recording parameters relating to the well-being of a user which comprises: sensing a user's activity using a sensing means and recording said activity on a recording means functionally coupled thereto; entering subjective information into at least one input module which information is also recorded on said recording means; and selectively recalling said recording information as required.

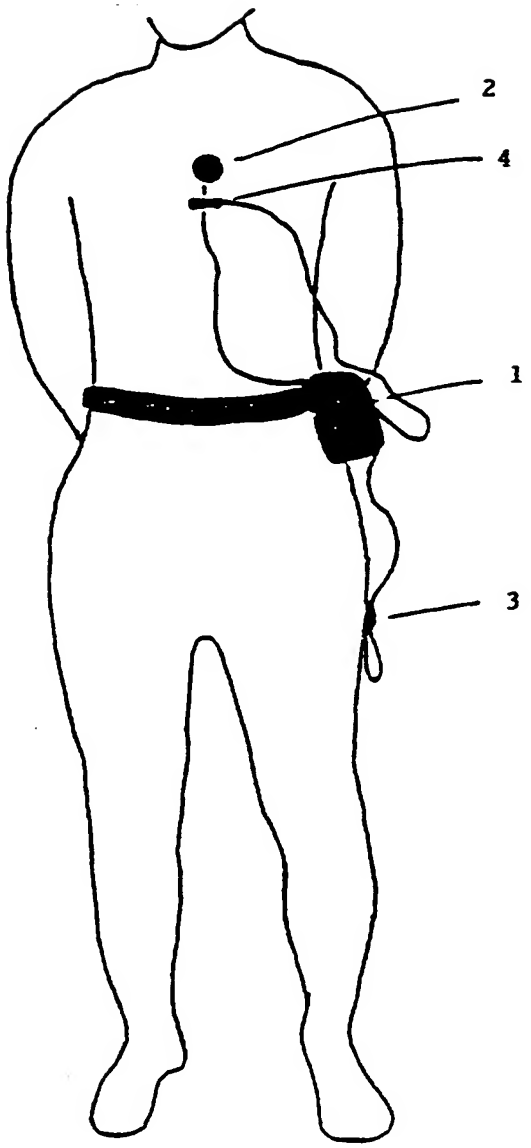


Figure 1

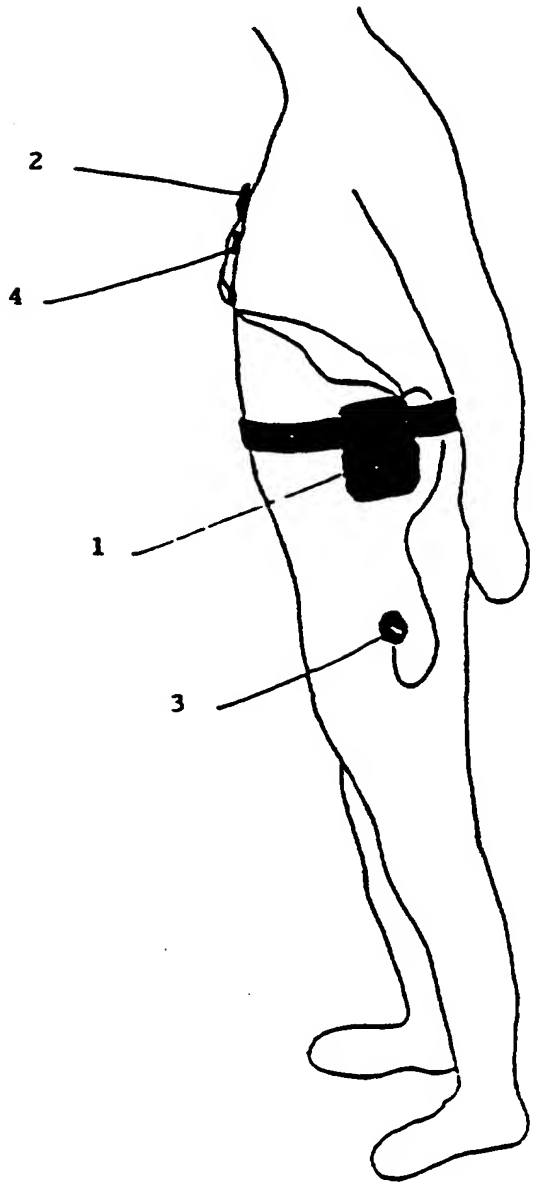


Figure 2

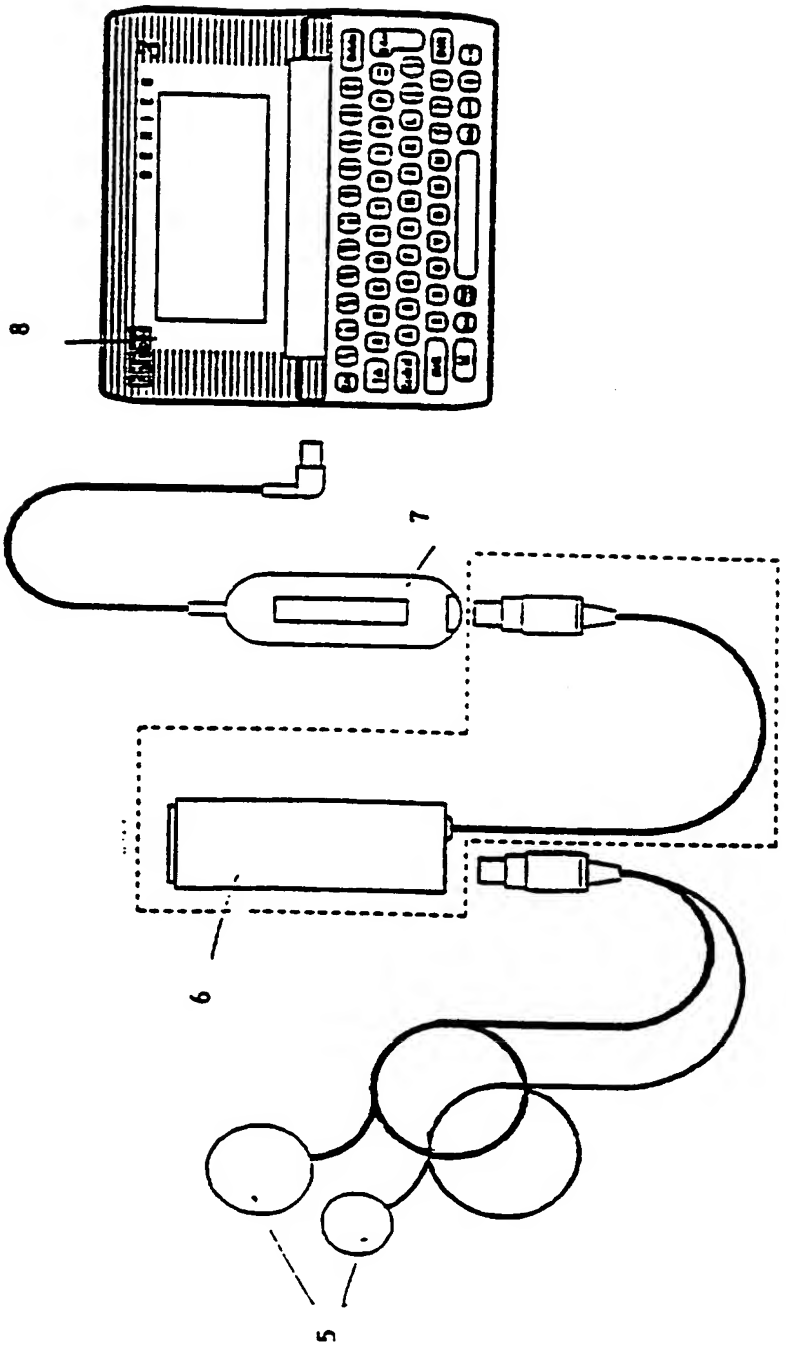


Figure 3

Fig 4

A SAMPLE 50 SECOND TRACE DEMONSTRATING CHANGE IN POSTURE, WALKING SLOWLY AND WALKING MORE QUICKLY.

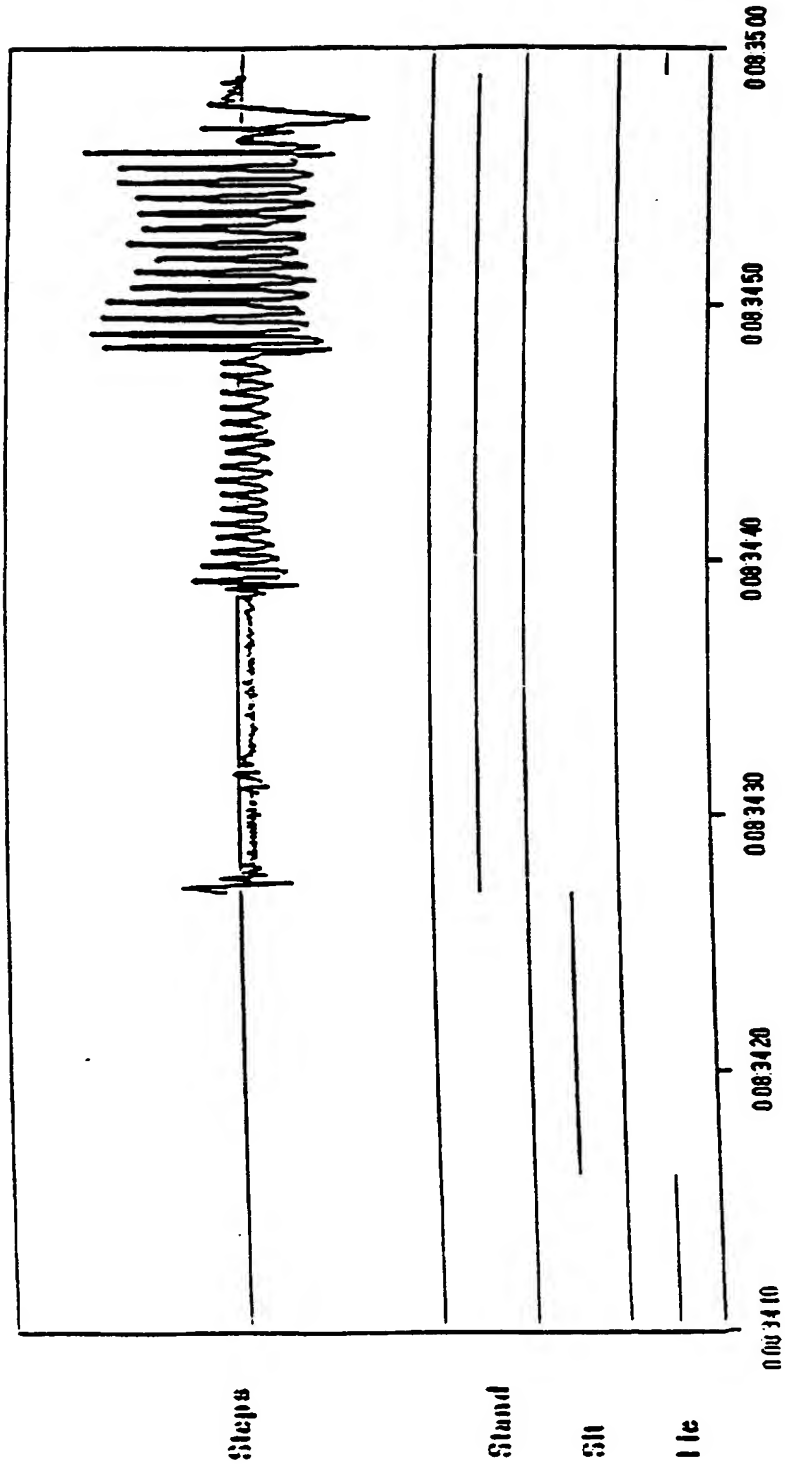


Fig 5

A 24 HOUR SUMMARY OF ACTIVITY. EACH DOT REPRESENTS A STEP AND THE HEIGHT ABOVE THE THRESHOLD IS A MEASURE OF THE VIGOUR

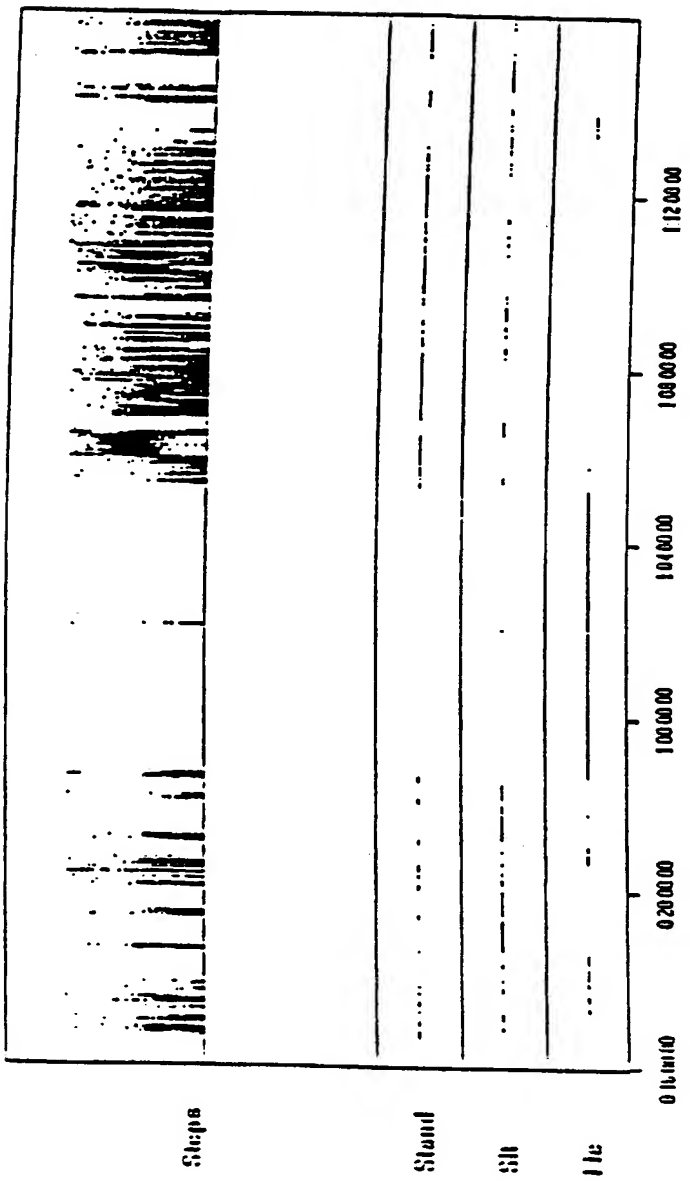


Figure 6

50 LARGE STRIDES TAKEN DELIBERATELY AND DISPLAYED ON A 50 SECOND TRACE

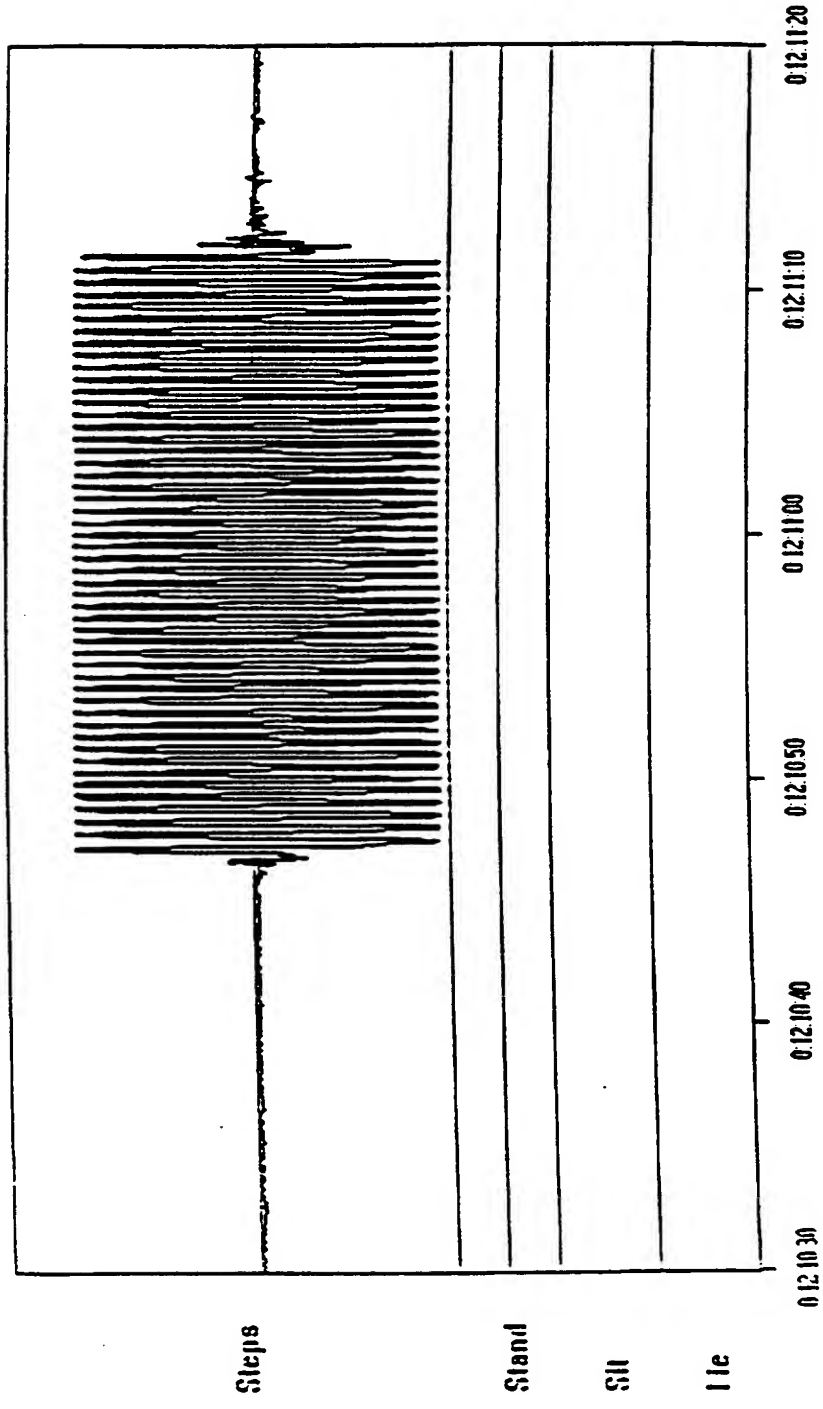


Fig 7

Simultaneous Recordings from 2 Systems Worn Concurrently

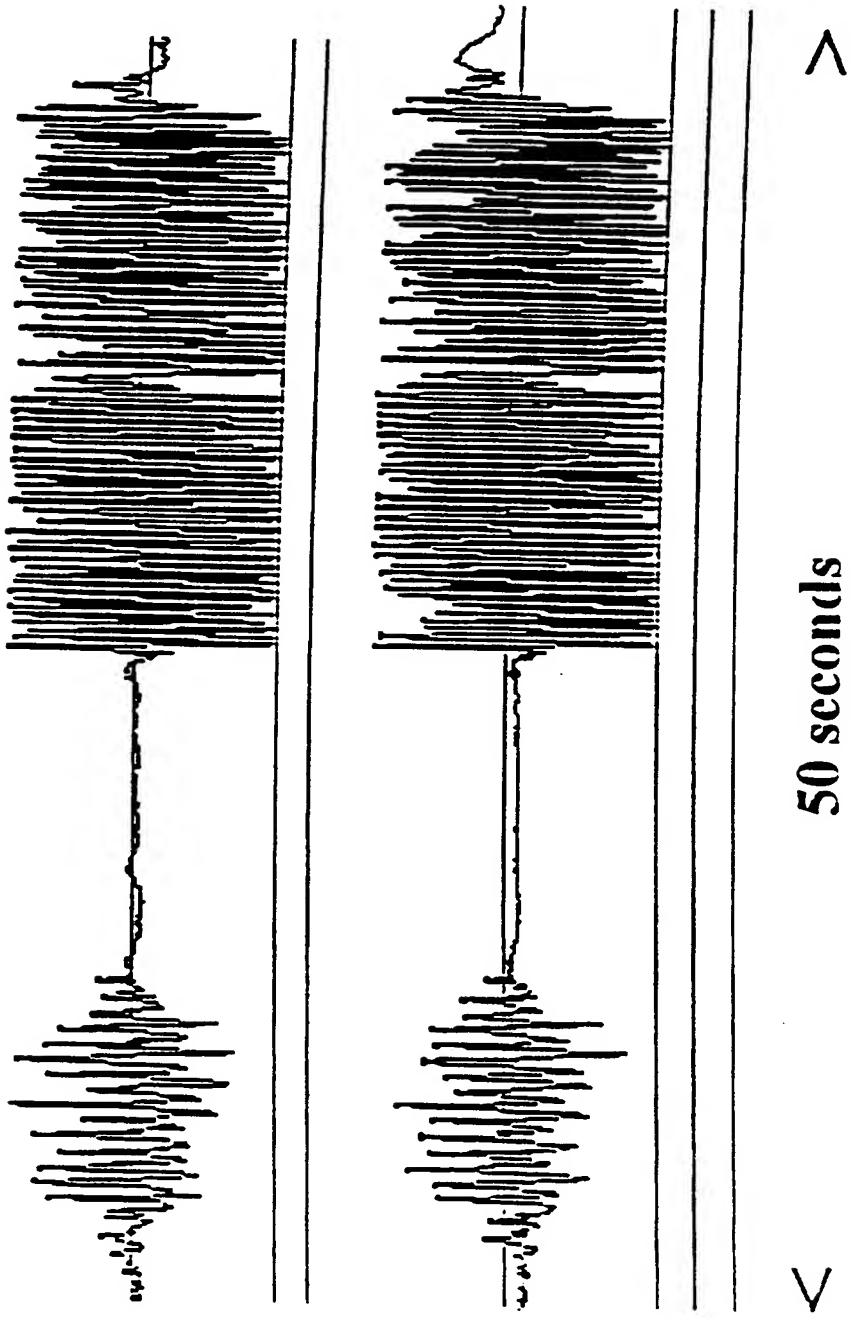


Fig 8

AVERAGE AMPLITUDE OF ACCELEROMETER DEVIATION PER STEP
(MEAN & 95% CI)
FOR NORMALS (HAQ - 0) MILD RHEUMATOID ARTHRITIS (HAQ 0.5 - 1.5) AND SEVERE RA (HAQ 2 - 3)

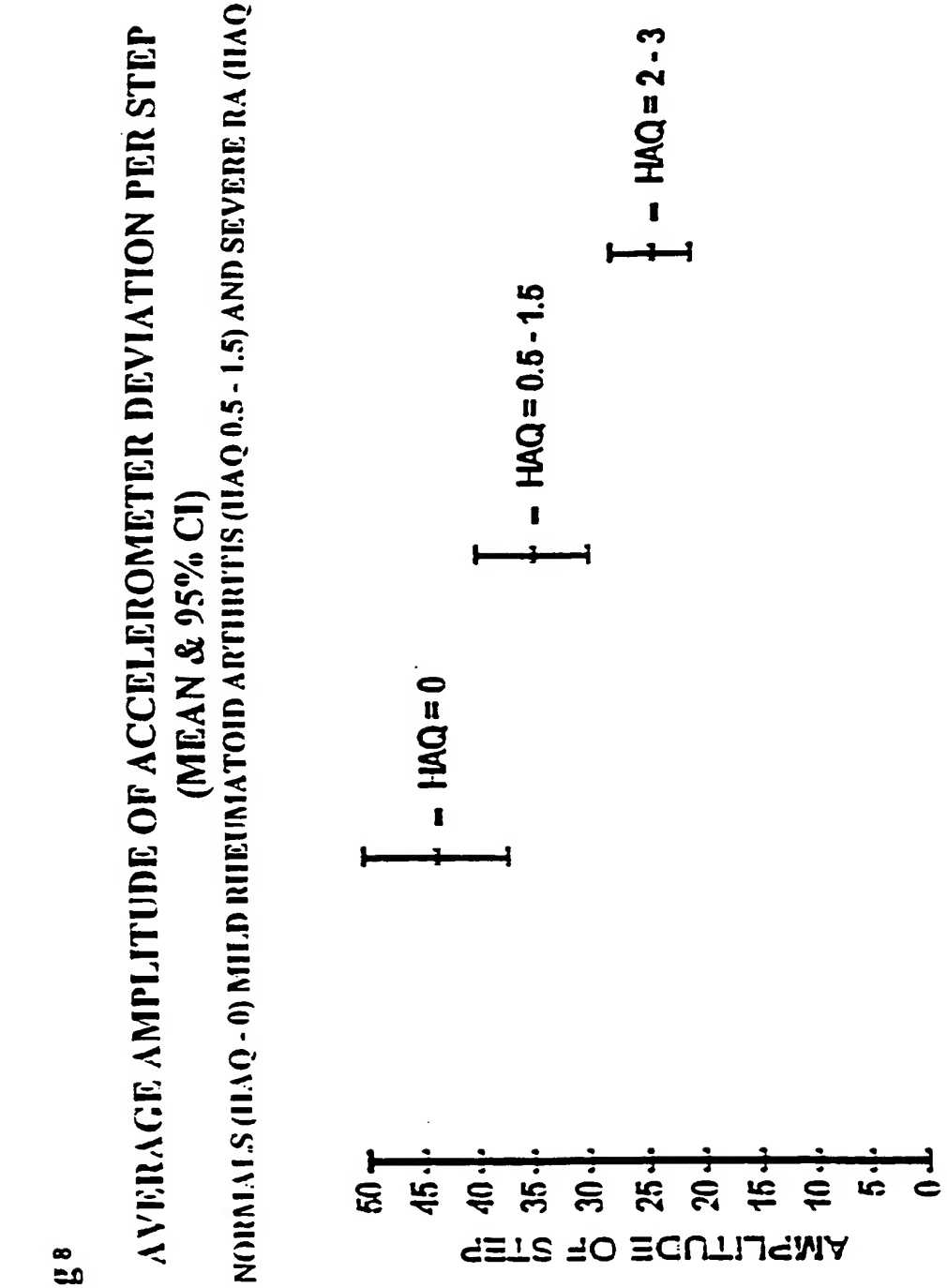


Fig 9

24 HOUR ENERGY TOTAL (MEAN & 95% CI)

FOR NORMALS (IIAQ - 0) MILD RHEUMATOID ARTHRITIS (IIAQ 0.5 - 1.5) AND SEVERE RA (IIAQ 2 - 3)

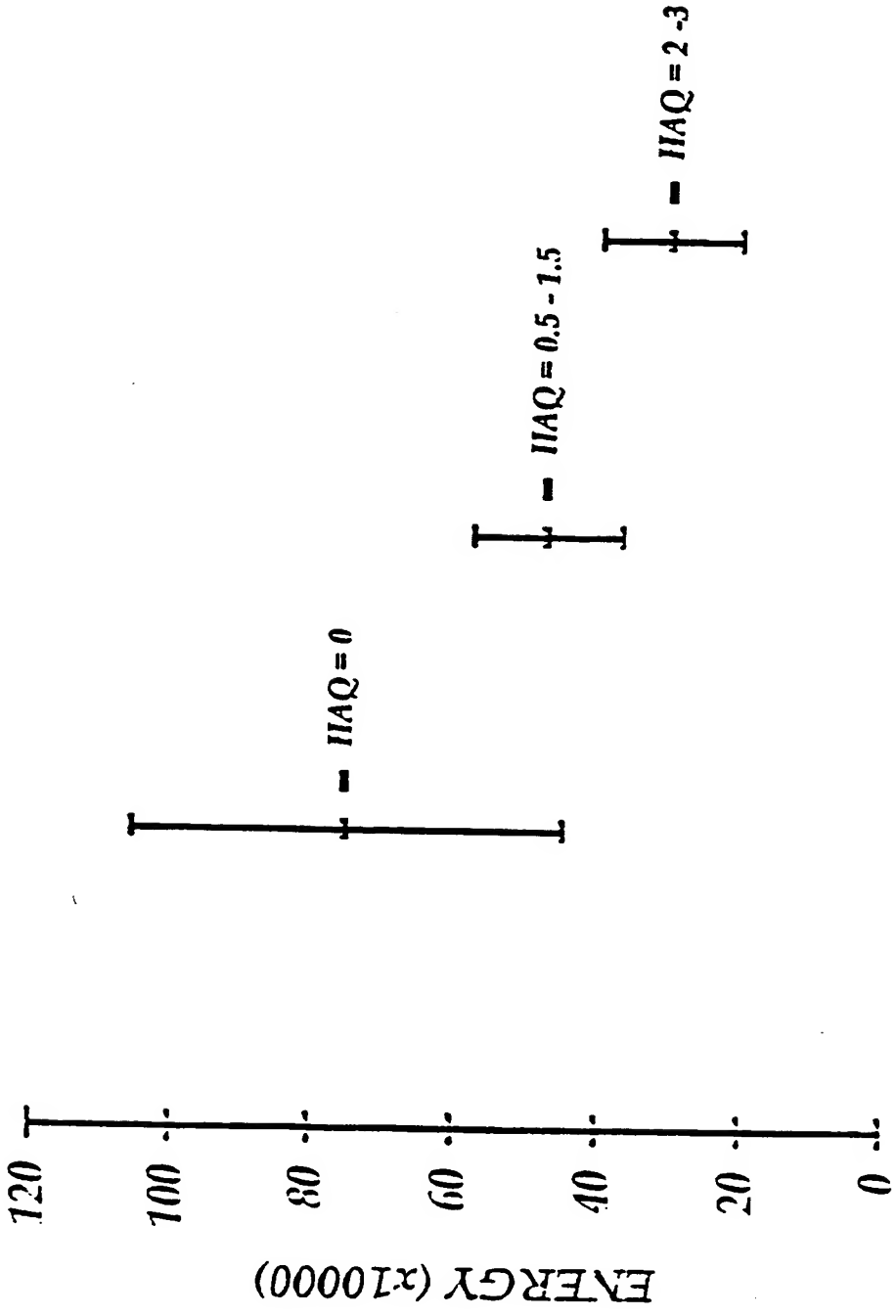


Fig 10

ENERGY (NUMBER x AMPLITUDE OF STEPS) PER MINUTE AS MEASURED BY THE NUMACT PLOTTED AGAINST METS FROM THE BRUCE PROTOCOL

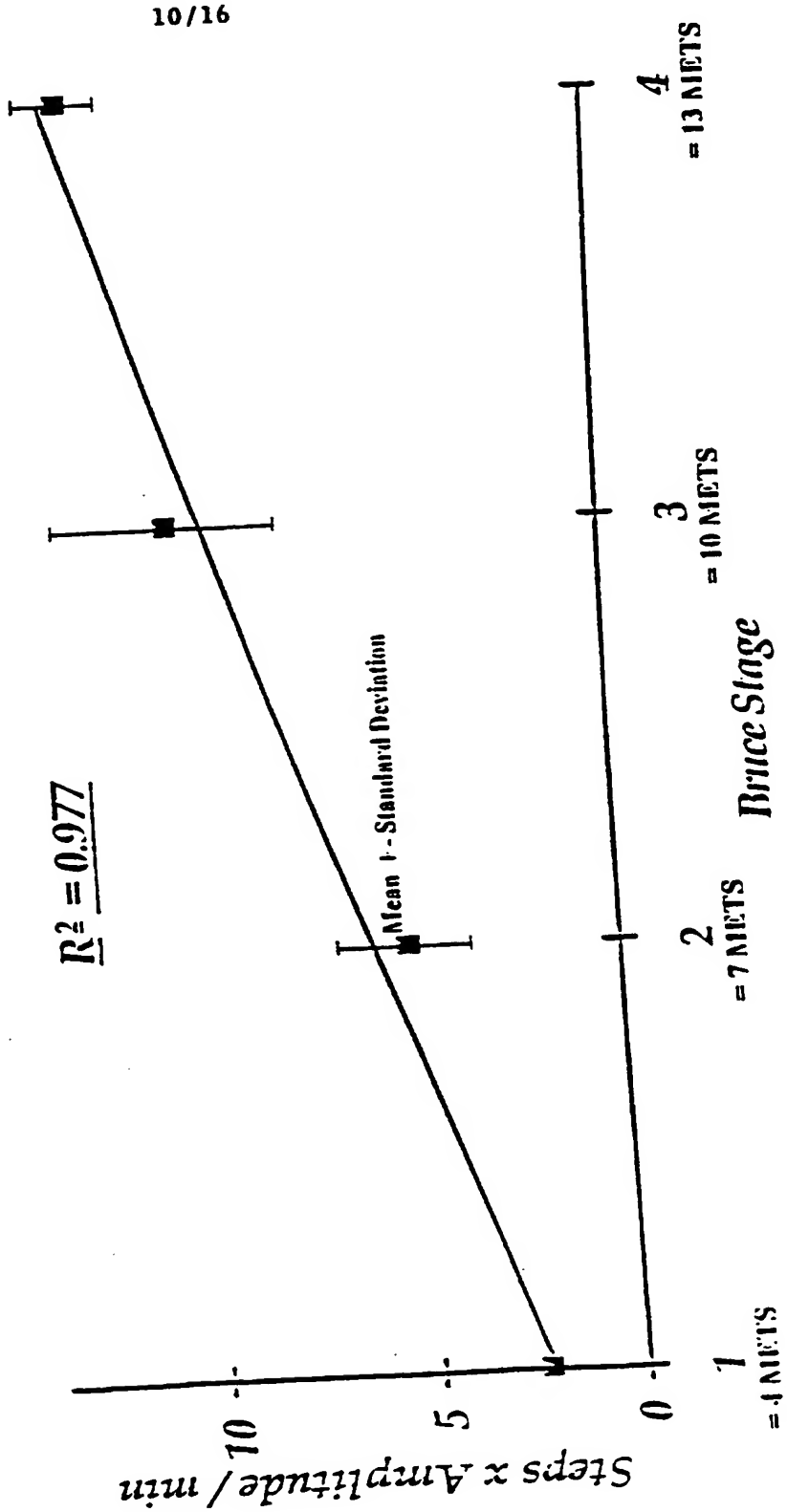


FIGURE 11 SHOWING RELATIONSHIP OF PAIN SCORING TO ACTIVITY THROUGH THE DAY-SHOWING GREATER ACTIVITY AT TIMES OF LOW PAIN

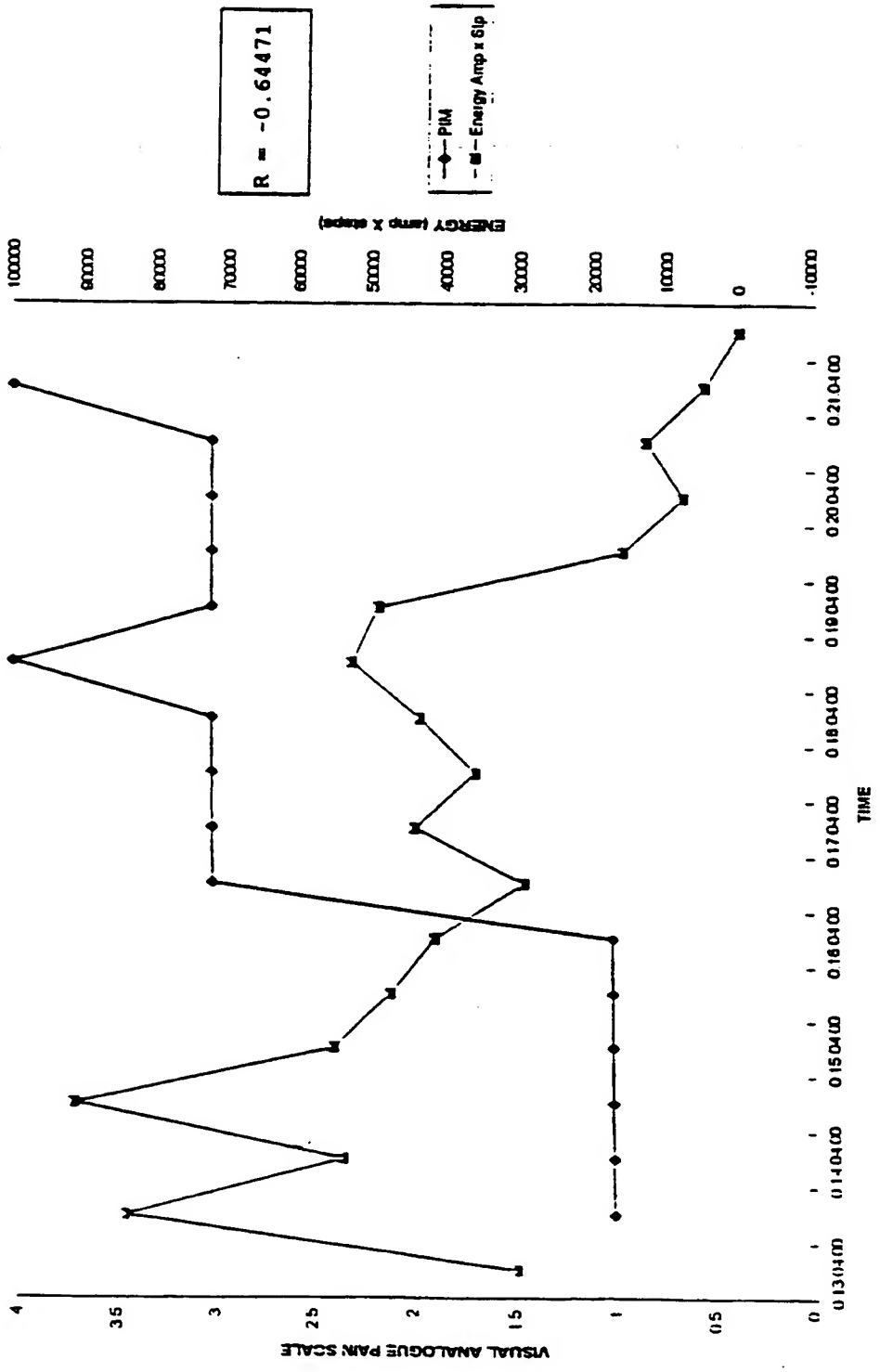


Figure 11

Table 1

A COMPARISON OF NUMBER OF STEPS COUNTED BY TWO OBSERVERS WATCHING A VIDEO OF ACTIVITY AS RECORDED BY THE NUMACT.

TEST No	DURATION	No of STEPS COUNTED			DIFFERENCE	OBSERVER 1 -	OBSERVER 2 -	OBSERVER 1 -
	MINUTES	OBSERVER 1	OBSERVER 2	NUMACT		NUMACT	NUMACT	OBSERVER 2
A	3	250	253	258		-8	-5	-3
B	3	273	269	273		0	-4	4
C	1	86	82	82		4	0	4
D	1	44	45	53		-9	-8	-1
E	1	62	62	63		-1	-1	0
F	1	76	75	73		3	2	1
G	1	31	33	36		-5	-3	-2
					MEAN	-2.28571	-2.71429	0.428571
					STDEV	6.154748	3.352327	2.760262
					95% LoA	10.3095	6.704654	5.520524

Table 2

LIMITS OF AGREEMENT BETWEEN TWO SYSTEMS WORN SIMULTANEOUSLY

DURATION		AVE AMPLITUDE OF RECORDINGS						DIFFERENCE
6 HRS		SYSTEM 1	38.594	v'	SYSTEM 2	40.5797		-1.9857
2 HRS		SYSTEM 1	48.1455	v'	SYSTEM 2	48.4989		-0.3534
1 HR		SYSTEM 5	41.5502	v'	SYSTEM 6	42.9001		-1.3499
1 HR		SYSTEM 6	42.9001	v'	SYSTEM 7	43.7694		-0.8693
1 HR		SYSTEM 7	43.7694	v'	SYSTEM 5	41.5502		2.2192
							MEAN	-0.46782
							STDEV	1.618362
							95% LoA	3.236724

TABLE 3

THE VARIATION IN 24 HOUR ENERGY USAGE FOR THE SAME PERIOD OF THE WEEK, ONE WEEK APART.

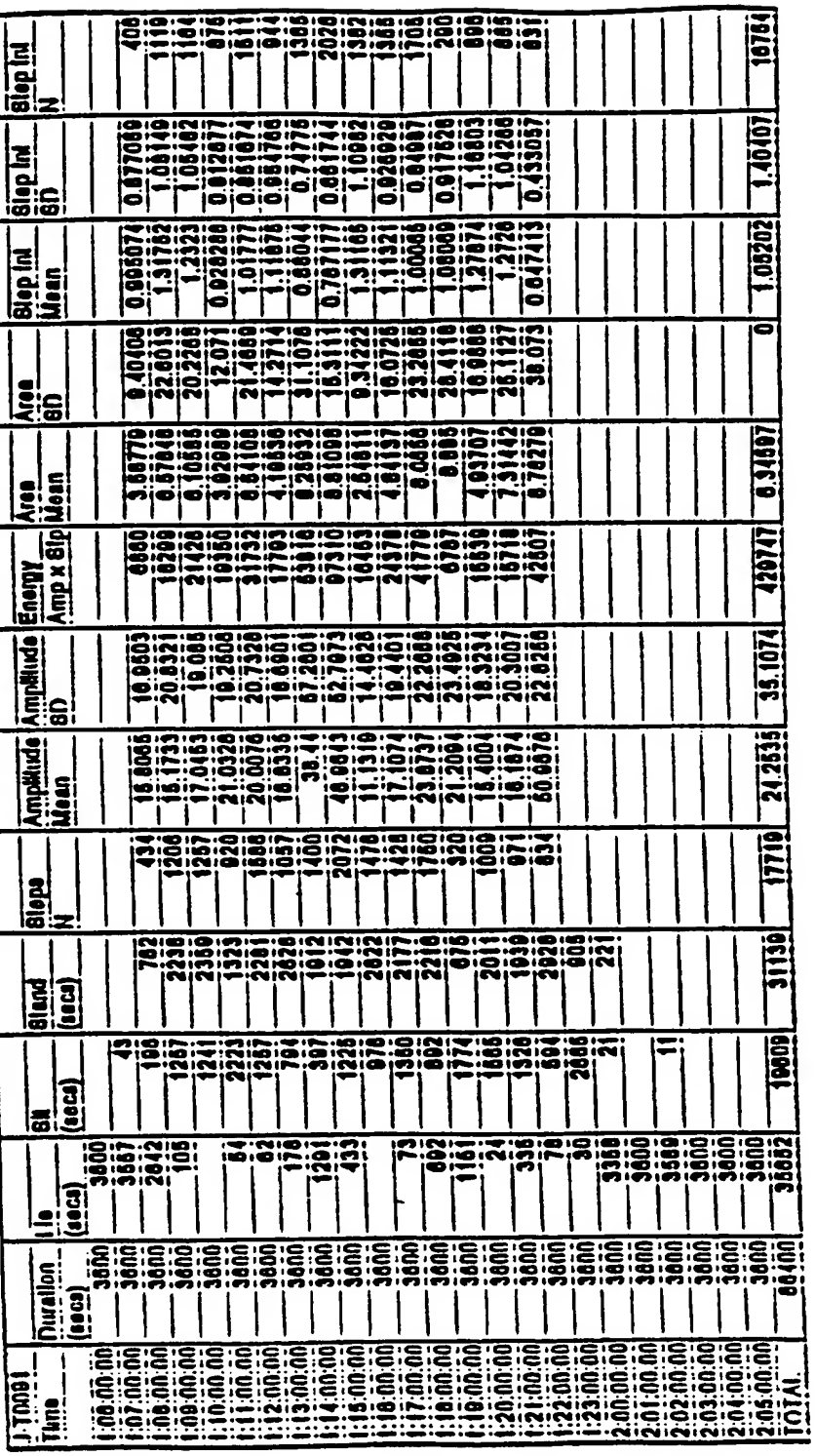
ENERGY PATIENT	WEEK 1	WEEK 2	DIFFERENCE	% AGGREEMENT
101	196338	REC 5		
103	93479	74405	-19074	79.59542
105	331589	294513	-37076	88.81869
106	556772	349372	-207400	62.74956
108	430530	456691	26161	94.27162
109	429747	508272	78525	84.55059
110	211298	181781	-29517	86.03063
111	521944	659533	137589	79.13842
112	584070	810791	226721	72.03706
			DIFFERENCE	% AGGREEMENT
		MEAN	21991.13	80.899
		STDEV	130350.8	9.9567
		LoA	260701.6	

SUBSTITUTE SHEET (RULE 26)

TABLE 4

THE VARIATION IN 24 HOUR ENERGY USAGE IN TWO CONSECUTIVE 24 HOUR PERIODS

ENERGY PATIENT	DAY 1	DAY 2	DIFFERENCE	% AGGREEMENT
101 P REC 3	196338	185000	11338	94.225265
103 A REC 4	71784	108619	-36835	66.087885
106 P REC 2	453702	346779	106923	76.433209
108 P REC 3	430530	545874	-115344	78.869849
109 P REC 2	188995	247914	-58919	76.234097
110 A REC 4	199720	121737	77983	60.953835
111 A REC 3	605562	855203	-249641	70.809153
112 A REC 3	810791	482980	327811	59.568989
		DIFFERENCE		% AGREEMENT
MEAN		7914.5		72.897785
STDEV		171153.44		11.245374
LOA		342306.88		



J:T0001 Time	Duration (secs)	I/e (secs)	BK (secs)	Blend (secs)	Blips N	Amplitude Mean	Amplitude BD	Energy Amp x Blp	Area Mean	Area BD	Blop Ind Mean	Blop Ind BD	Blop Ind N
1:06:00:00	3600	3600	43										
1:07:00:00	3600	3567	100	782	434	16.8065	10.9503	6660	3.66770	9.40406	0.995074	0.877080	406
1:08:00:00	3600	2642	105	2238	1206	16.1733	20.8321	16200	6.67848	22.6013	1.31762	1.08149	1119
1:09:00:00	3600	1267	1241	2360	1267	17.0463	18.085	21428	8.10666	20.2268	1.2323	1.05462	1164
1:10:00:00	3600	1241	84	1323	920	21.0328	19.2808	18350	3.02000	12.071	0.928288	0.912877	876
1:11:00:00	3600	2223	62	2281	1886	20.0076	20.7328	31732	8.81108	21.4660	1.01777	0.861674	1611
1:12:00:00	3600	1267	170	2626	1057	16.8336	18.6001	17703	4.19536	14.2714	1.11878	0.984766	944
1:13:00:00	3600	704	397	1012	1400	38.44	67.2001	63016	0.25832	31.1076	0.66044	0.74776	1306
1:14:00:00	3600	1261	1226	1042	2072	46.0613	62.7073	97310	0.81008	15.3111	0.767177	0.661744	2026
1:15:00:00	3600	433	978	2822	1470	11.1310	14.4026	16463	2.84011	9.34222	1.31166	1.10662	1382
1:16:00:00	3600	973	1380	2177	1428	17.1074	19.4401	24370	4.84197	16.0728	1.11321	0.926020	1366
1:17:00:00	3600	802	802	2210	1760	23.0737	22.2008	41770	8.0488	23.2685	1.00068	0.840087	1708
1:18:00:00	3600	1161	1774	676	920	21.2064	23.4026	6767	0.805	28.4116	1.08069	0.917628	200
1:19:00:00	3600	24	1666	2011	1009	16.4004	18.3234	16630	4.03707	16.0666	1.27674	1.16803	898
1:20:00:00	3600	336	1920	1930	971	16.1674	20.3007	15718	7.31442	26.1127	1.2726	1.04266	885
1:21:00:00	3600	78	804	2820	834	60.0878	22.6288	42807	0.78278	38.073	0.647413	0.433057	831
1:22:00:00	3600	30	2666	606									
1:23:00:00	3600	21	3388	221									
2:00:00:00	3600		3600										
2:01:00:00	3600	11	3589										
2:02:00:00	3600		3600										
2:03:00:00	3600		3600										
2:04:00:00	3600		3600										
2:05:00:00	3600		3600										
TOTAL	86400	35882	19609	31130	17719	24.2535	35.1074	429747	8.34697	0	1.08202	1.40107	16784

TABLE 5

INTERNATIONAL SEARCH REPORT

In. ional Application No
PCT/GB 96/00603

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B5/11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US,A,5 263 491 (W. THORNTON) 23 November 1993	1,22
A	see column 2, line 56 - column 3, line 66 see column 4, line 37 - line 67 see column 5, line 51 - line 68 see column 6, line 64 - column 7, line 16; figures 1,6	2-4,6,7, 9,10,12, 13, 17-19,21

Y	US,A,5 361 755 (M. SCHRAAG) 8 November 1994	1,22
A	see column 5, line 10 - line 55 see column 7, line 34 - line 54; figures 1,2	14-17

	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
13 June 1996	27.06.95
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+ 31-70) 340-3016	**Authorized officer** Fontenay, P

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INTERNATIONAL SEARCH REPORT

Inte ›nal Application No
PCT/GB 96/00603

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	PROCEEDINGS OF THE EIGHTH ANNUAL CONFERENCE OF THE IEEE ENGINEERING IN MEDICINE AND BIOLOGY SOCIETY, vol. 1, 7 - 10 November 1986, TORT WORTH - TEXAS (US), pages 579-583, XP002005517 R. M. GLASER: "A system for monitoring daily ambulatory activit " see the whole document ---	1-8,12, 13,22
A	EP,A,0 535 508 (VITATRON MEDICAL BV) 7 April 1993 see column 7, line 30 - column 8, line 28; figures see column 3, line 43 - column 4, line 30 ---	1,9,10, 14-16, 18,20-22
A	EP,A,0 062 459 (NATIONAL RESEARCH DEVELOPMENT CORP.) 13 October 1982 see page 3, line 3 - line 29 -----	1,9-11, 22

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Int. ...onal Application No
PCT/GB 96/00603

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-5263491	23-11-93	NONE	
US-A-5361755	08-11-94	NONE	
EP-A-535508	07-04-93	US-A- 5293879 DE-D- 69208791	15-03-94 11-04-96
EP-A-62459	13-10-82	GB-A,B 2096319 US-A- 4437473	13-10-82 20-03-84